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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/998,167	12/03/2001	Xudong Dai		6187
7590	05/04/2004		EXAMINER	
Tong Fong 20 Berkley Court Morganville, NJ 07751			MAHATAN, CHANNING	
			ART UNIT	PAPER NUMBER
			I631	

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/998,167	DAI ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Channing S Mahatan	1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 11 February 2004.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 1-5 and 10-15 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 6-9 is/are rejected.
- 7) Claim(s) 6 is/are objected to.
- 8) Claim(s) 1-15 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 04 March 2002 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All
  - b) Some \*
  - c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

**DETAILED ACTION**

*APPLICANTS' ELECTION*

Applicants' election of Group II (claims 6-9; drawn to an apparatus wherein gene expression profile is processed to provide a plurality of gene expression pattern to permit maximal separation among gene expression pattern) in the response, filed 11 February 2004, is acknowledged. Although, Applicants' did not specifically state the election is "with traverse" or "without traverse" Applicants' have presented arguments for the reconsideration of the Restriction/Election requirement. Therefore, to assist in clarification of the record the election is considered an election "with traverse", wherein the traversal is on the ground(s) that 1) Group III claims are directed to a more specified component of the method disclosed by Group I claims; and 2) the apparatus disclosed by Group II is to be implemented in carrying out the method disclosed by Groups I and III. However, this is not found persuasive on the grounds that: 1) Group I is directed to a method of detecting gene expression patterns whereas Group III is directed to a method of extracting gene expression signature utilizing wavelets, therefore having different functions, effects, and modes of operation; and 2) Groups I and III do not specifically require the apparatus of Group I to for the implementation of the claimed method(s).

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-5 and 10-15 are withdrawn from further consideration pursuant to 37 C.F.R. § 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

*CLAIMS UNDER EXAMINATION*

Claims herein under examination are claims 6-9.

**Claims Rejected Under 35 U.S.C. § 112 1<sup>st</sup> Paragraph**

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

*LACK OF WRITTEN DESCRIPTION AND LACK OF ENABLEMENT*

Claims 6-9 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 6-9 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 6-9 are rejected under 35 U.S.C. § 112, first paragraph, wherein the instant claims recite the limitations an “gene order library” (claim 8), “gene order selection” (claim 8), and “error examiner” (claim 9) which are not properly described and thus not enabled. It should be noted claims 6 and 7 also include these embodiments and therefore are herein rejected. The specification is deficient in defining the structural and functional features of a “gene order library”, “gene order selection”, and “error examiner”. Thus, it is unclear what Applicants intend the said limitations to be and the functions therein for the instantly claimed apparatus. For instance, what function(s)/operation(s) does the “gene order library”, “gene order selection”, and

Art Unit: 1631

“error examiner” perform in the instantly claimed apparatus? What is a “gene order library” or “gene order selection”? How does the “error examiner” examine? What error(s) does the “error examiner” identify? What does the identified error(s) mean in the context of the apparatus? Is the error(s) to be utilized in another device of the claimed apparatus? In the absence of a definition or limitations for these phrases one skilled in the art would not know what to make and how to use the apparatus as claimed.

Additionally, claim 8 broadly embraces other “frequency domain converter”(s) (implied by the preferred embodiment language) and therefore the claims are not commensurate in scope with the disclosure. The “frequency domain converter” is disclosed as being:

“Frequency domain information converter (13): In the example of the preferred embodiment of the proposed invention, the energy features of are used to represent the gene expression pattern information in frequency domain. The energy measure  $X_j$  of a frequency subband  $j$  is defined as:

$$X_j = \frac{1}{m_j} \sum_{i=1}^{m_j} y_{ij}^2$$

where  $y_{ij}$  is the  $i^{th}$  wavelet coefficient of subband  $j$  and  $m_j$  is the total number of wavelet coefficients of subband  $j$ . In the normalized energy measure, each wavelet coefficient is centered on the mean. That is

$$x_j = \frac{1}{m_j} \sum_{i=1}^{m_j} (y_{ij} - \mu_j)^2$$

Where

$$\mu_j = \frac{1}{m_j} \sum_{i=1}^{m_j} y_{ij}$$

However, no other “frequency domain converter”(s) are disclosed and the operations performed therein. The specification discloses only the above cited section of the specification for the

“frequency domain converter”. None of these above disclosed elements are limitations of the instant claim. The specification does not provide guidance, direction, or examples as to other ways for the construction or operation of a “frequency domain converter”. Thus, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

### **Claims Rejected Under 35 U.S.C. § 112 2<sup>nd</sup> Paragraph**

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6-9 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

#### *VAGUE AND INDEFINITE*

Claim 6 recites the following:

“An apparatus wherein gene expression patterns are identified by gene expression signatures derived from gene expression profiles”

which is considered vague and indefinite. The instant claim lacks any defining structural characteristics (i.e. devices) for the apparatus other than the apparatus having gene expression patterns. Therefore, the claim is viewed as any apparatus as long as it possesses gene expression patterns. No functions of the instantly claimed apparatus are indicated. Clarification of the metes and bounds, via clearer claim language, is requested.

Claim 7 recites the term “associated”/“association” which is vague and indefinite. It is unclear the criteria(s) that establishes “genes” and “permutations of biological function and

status” to be associated with each other. Applicants can resolve this issue by particularly pointing out the criteria that formulates said association. Clarification of the metes and bounds, via clearer claim language is requested.

Claim 8 recites the limitation “gene order library” which is vague and indefinite. It is unclear what Applicants’ regard a “gene order library” to be and/or encompass. Applicants’ can resolve this issue by particularly pointing out what is regarded as a “gene order library”. Additionally, the specification provides no definition or limitation(s) for the above language. Clarification of the metes and bounds, via clearer claim language is requested.

Claim 8 recites the limitation “gene order selection device” which is vague and indefinite. It is unclear what Applicants’ regard a “gene order selection device” to be and/or encompass. Applicants’ can resolve this issue by particularly pointing out what is regarded as a “gene order selection device”. Additionally, the specification provides no definition or limitation(s) for the above language. Clarification of the metes and bounds, via clearer claim language is requested.

Claim 9 recites the limitation “error examiner” which is vague and indefinite. It is unclear what Applicants’ regard an “error examiner” to be and/or encompass. Applicants’ can resolve this issue by particularly pointing out what is regarded as a “error examiner”. Additionally, the specification provides no definition or limitation(s) for the above language. Clarification of the metes and bounds, via clearer claim language, is requested.

**Claims Rejected Under 35 U.S.C. § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 6 and 7 are rejected under 35 U.S.C. § 102(a) as being anticipated by Myasnikova et al.

Myasnikova et al. describes the construction of an integrated map of *Drosophila melanogaster* segmentation gene expression from embryos (Abstract). Gene expression data was acquired by confocal scanning microscopy (claim 6; page 3, right column, lines 9-13; page 4, right column, lines 3-41). The authors indicate the gene expression patterns are viewed as a collection of ‘domains’ (i.e. frequency domains) each of which is a region of expression containing one concentration maximum (claim 7; pages 3-4, beginning on the right column, line left column, line 34). Myasnikova et al. extracts features from the gene expression patterns by wavelet transformation utilizing a computer platform (claim 7; page 4, right column, lines 35-40; pages 5-10), wherein the said computer platform is viewed as Applicants’ apparatus. The authors discuss the classification (i.e. clustering) of the gene expression patterns based on temporal and spatial groups (claim 7; pages 4-5, beginning on the left column, line 42; and page 10, beginning on the left column, line 8). Thus, Myasnikova et al. anticipates the instantly claimed invention.

*OBJECTION TO CLAIM*

Claim 6 is objected to because of a missing a period (.) at the end of the claim.

**No Claims Are Allowed.**

*EXAMINER INFORMATION*

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Channing S. Mahatan whose telephone number is (571) 272-0717. The Examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina M. Plunkett, whose telephone number is (571) 272-0549 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date: *April 29, 2004*

Examiner Initials: *C.S.M.*

*Marianne P. Allen*  
MARIANNE P. ALLEN 5/3/04  
PRIMARY EXAMINER  
*All1631*